



**UNITED STATES DEPARTMENT OF COMMERCE**  
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
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09/242,343 04/12/99 VOLLENBROICH

D 2694-119P

002292 HM22/0315  
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EXAMINER

BRUMBACK, E  
ART UNIT PAPER NUMBER

1642  
DATE MAILED:

13

03/15/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Advisory Action

Application No.

09/242,343

Applicant(s)

Vollenbroich et al.

Examiner

Brenda Brumback

Group Art Unit

1642



THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☒ expires 4 months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on \_\_\_\_\_ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Feb 26, 2001 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☒ The proposed amendment(s):

- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
- ☒ will not be entered because:
- ☒ they raise new issues that would require further consideration and/or search. (See note below).
- ☐ they raise the issue of new matter. (See note below).
- ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See attached.

☒ Applicant's response has overcome the following rejection(s):

See attached.

- ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.
- ☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attached.
- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):
- Claims allowed: \_\_\_\_\_
- Claims objected to: \_\_\_\_\_
- Claims rejected: 1-17
- ☐ The proposed drawing correction filed on \_\_\_\_\_ ☐ has ☐ has not been approved by the Examiner.
- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Other

*Brenda Brumback*  
BRENDA BRUMBACK  
PATENT EXAMINER

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## **DETAILED ACTION**

### ***Attachment to Advisory Action***

1. Applicant's proposed amendment to claim 1 to add the limitation of an inactivation factor  $>10^4$  raises new issues under 35 U.S.C. 112, second paragraph, as it is unclear what unit of measurement  $10^4$  denotes. Thus, the metes and bounds of the claimed invention cannot be determined and the claim is indefinite.
2. Applicant's newly proposed claim 18 raises a new issue of inactivating viruses in blood products, as this limitation has not previously been addressed and may raise new issues under 35 U.S.C. 112, first paragraph.
3. Applicant's newly proposed claim 19 raises new issues under 35 U.S.C. 112, first and second paragraphs, for recitation of vaccines isolated from blood, because the art teaches that blood products do not encompass vaccines. Furthermore, the claim is indefinite for recitation of plasma derivatives because the disclosure fails to teach the metes and bounds of such derivatives.
4. If entered, applicant's proposed amendment to claim 1 would overcome the rejection of claims 1-10 under 35 U.S.C. 112, first and second paragraphs, for inactivation of viruses in cell cultures using concentrations greater than 70  $\mu\text{M}$  and the rejection of claim 10 for recitation of herpesviruses. Herpesvirus would be understood to mean any of the family *Herpesviridae*, as per

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applicant's arguments and Exhibit A. However, applicant's arguments and Exhibit A would not overcome the rejection of claim 10 for recitation of immunodeficiency viruses, because there does not appear to be a well-defined family or group of viruses which are referred to in the art as immunodeficiency viruses.

5. If entered, applicant's proposed claim amendments would overcome the rejection of claims 1, 3, 4-7, 9, and 10 under 35 U.S.C. 103(a) as unpatentable over Itokawa et al. and the rejection of claim 2 under 35 U.S.C. 102(a) as unpatentable over Itokawa et al. in view of Horowitz et al.

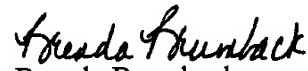
6. If entered, applicant's proposed amendments and arguments would not overcome the rejection of claims 1, 3, 9, and 10 under 35 U.S.C. 103(a) as unpatentable over Naruse et al. or the rejection of claim 2 under 35 U.S.C. 103(a) as unpatentable over Naruse et al. in view of Horowitz et al. Applicant argues that the present method is directed to a method of directly inactivating viruses, whereas Naruse et al. is directed to an indirect method inactivating viruses. However, it is noted that the feature upon which applicant relies (i.e. direct inactivation of viruses) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

March 13, 2001

  
Brenda Brumback,  
Patent Examiner